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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,098	10/14/2004	Akira Ideno	Q83564	9139
23373 7590 11/13/2009 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER PROUTY, REBECCA E				
ART UNIT		PAPER NUMBER		
1652				
NOTIFICATION DATE		DELIVERY MODE		
11/13/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO@SUGHRUE.COM
PPROCESSING@SUGHRUE.COM

Office Action Summary

Application No.

10/511,098

Applicant(s)

IDENO ET AL.

Examiner

Rebecca E. Prouty

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-36, 41, 42, 53-56 and 59-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-36, 41, 42, 53-56 and 59-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Claims 1-33, 37-40, 43-52, and 57-58 have been canceled.
Claims 34-36, 41, 42, 53-56 and 59-64 are still at issue and are present for examination.

Applicants' arguments filed on 8/3/09, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 34, 35, 36, 42, 53-56, and 59-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz et al. (US PG-PUB 2003/0096352) in view of Iida et al. (Reference 1 of Applicants IDS of 12/1/09). The rejection is explained in the previous Office Action and is now applied to all claims indicated in view of applicants amendments to the claims.

Applicants argue that there is no reason why one of ordinary skill in the art would modify Scholz's expression vector to incorporate Iida's archaeobacterial FKBP-type PPIase. However, this is not persuasive as the rejection suggests a simple substitution of one element of the vector of Scholz et al. with a another similar element taught in the prior art providing all the same features as the replaced element. As discussed in MPEP 2143, The Supreme Court in *KSR* identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham*. Exemplary rationales that may support a conclusion of obviousness include:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to

Art Unit: 1652

modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Thus the instant rejection is an example of (B) above and clearly does provide a rationale to modify Scholz's vector (i.e., the archeabacterial FKPP PPIase of Iida et al. would provide all the same features as the chaperone polypeptides which are PPIases taught by Scholz et al.

Applicants further argue that the presently claimed expression vector possesses an unexpectedly superior property in that it produces a fused protein with hardly expressible proteins in a soluble form in a large amount and effectively. However, this is not persuasive as there is no evidence of how much soluble protein is produced by the vectors of Scholz et al. Clearly from the examples of Scholz et al. some of the recombinant fusion proteins were produced as easily solubilized inclusion bodies, but there is no indication that there was no soluble protein produced and the proteins expressed by Scholz et al. were not the same as the proteins produced by applicants such that the results are not directly comparable. Furthermore, even if the TcFKBP18 vector disclosed in the specification produces increased levels of soluble proteins compared to the vector of Scholz et al., the unexpected results would not be commensurate in scope with the claims. Applicants claims recite

ANY archeobacterial FKBP-type PPIase having molecular chaperone activity comprising an IF domain. However, the *SlyD* protein disclosed by Scholz et al. is also an FKBP-type PPIase having molecular chaperone activity comprising an IF domain. Thus if applicants vectors exhibit superior properties to those of Scholz et al. the claims and the specification fail to identify the features of the vectors of applicants responsible for these unexpected properties. Applicants point to the Examiner previous statement that applicants previously provided sufficient information to conclude that the IF domain of archaeobacterial FKBP-type PPIase is critical for chaperone function of the PPIases and that other proteins with chaperone function but lacking any IF domain, do not show the same results. However, while applicants have demonstrated the importance of the IF domain it is noted that the *SlyD* proteins within the vectors of Scholz et al. also HAVE this domain and thus applicants have not demonstrated unexpected properties over the vectors of Scholz et al. nor identified what features of the claimed vectors are responsible for any such results that can be demonstrated.

Claims 34-36, 41, 53-56, and 59-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scholz et al. (US PG-PUB 2003/0096352) in view of Furutani et al. (see IDS of

Art Unit: 1652

7/23/08). The rejection is explained in the previous Office Action and is now applied to all claims indicated in view of applicants amendments to the claims.

Applicants argue that there is no reason why one of ordinary skill in the art would modify Scholz's expression vector to incorporate Furutani et al.'s archaeobacterial FKBP-type PPIase. However, this is not persuasive as the rejection suggests a simple substitution of one element of the vector of Scholz et al. with a another similar element taught in the prior art providing all the same features as the replaced element. As discussed in MPEP 2143, The Supreme Court in *KSR* identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in *Graham*. Exemplary rationales that may support a conclusion of obviousness include:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

Art Unit: 1652

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Thus the instant rejection is an example of (B) above and clearly does provide a rationale to modify Scholz's vector (i.e., the archeobacterial FKPP PPIase of Furutani et al. would provide all the same features as the chaperone polypeptides which are PPIases taught by Scholz et al.

Applicants further argue that the presence of a termination codon in the PPIase encoding sequence of Furutani et al. would render it unsuitable for producing a fusion protein as described by Scholz et al. However, this is not persuasive as any artisan even moderately skilled in the art of molecular biology would understand that when substituting the coding region for the protein of Furutani et al. into the vector of Scholz et al. to use ONLY the coding sequence and to NOT induce the termination codon. substituting only the coding region of the protein of Furutani et al. for the coding region of the chaperone polypeptide of the vectors of Scholz et al. would produce an operable vector.

Applicants further argue that the presently claimed expression vector possesses an unexpectedly superior property in that it produces a fused protein with hardly expressible proteins in a soluble form in a large amount and effectively. However, this is not persuasive as there is no evidence of how much soluble protein is produced by the vectors of Scholz et al. Clearly from the examples of Scholz et al. some of the recombinant fusion proteins were produced as easily solubilized inclusion bodies, but there is no indication that there was no soluble protein produced and the proteins expressed by Scholz et al. were not the same as the proteins produced by applicants such that the results are not directly comparable. Furthermore, even if the TcFKBP18 vector disclosed in the specification produces increased levels of soluble proteins compared to the vector of Scholz et al., the unexpected results would not be commensurate in scope with the claims. Applicants claims recite ANY archeabacterial FKBP-type PPIase having molecular chaperone activity comprising an IF domain. However, the *SlyD* protein disclosed by Scholz et al. is also an FKBP-type PPIase having molecular chaperone activity comprising an IF domain. Thus if applicants vectors exhibit superior properties to those of Scholz et al. the claims and the specification fail to identify

the features of the vectors of applicants responsible for these unexpected properties.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

Art Unit: 1652

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
Art Unit 1652